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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/166,701	10/05/1998	ISA ODIDI	SMI-005.01	9432
25181	7590	07/01/2004	EXAMINER	
FOLEY HOAG, LLP PATENT GROUP, WORLD TRADE CENTER WEST 155 SEAPORT BLVD BOSTON, MA 02110			WEBMAN, EDWARD J	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.



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09/166701

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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EXAMINER
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ART UNIT	PAPER NUMBER
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5/31/04

DATE MAILED:

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 5/10/04

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1, 4, 7-12, 23, 24-33 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
☐ Claim(s) \_\_\_\_\_ is/are allowed.  
☒ Claim(s) 1, 4, 7-12, 23, 24-33 is/are rejected.  
☐ Claim(s) \_\_\_\_\_ is/are objected to.  
☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.  
☐ The specification is objected to by the Examiner.  
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.  
☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892  
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  
☐ Interview Summary, PTO-413  
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948  
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4, 7-12, 23, 28-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guley et al in view of Jain et al.

Guley et al teach a controlled release (tablet) core comprising 20-0% drug and a 272% mixture of water soluble and water-insoluble polymers at a ratio of 10:1-1.5:1 (column 2 lines 27-36). Hydroxypropyl cellulose and carboxyl vinyl polymer are specified (column 2 lines 42 and 48-49). A coating comprising cellulose acetate phthalate is disclosed (column 3 line 19). Etodolac is specified (column 4 line 67). Lactose is disclosed (column 5 example 1). Sustained release is specified (Title). Excipients, including lubricants, are disclosed (column 3 lines 3-6). Talc and calcium stearate are specified (example 1 column 51). Guley et al further teach plural water soluble polymers including hydroxypropyl methyl cellulose and hydroxy propyl cellulose (column 2 lines 40-44). Plural water-insoluble polymers are specified including ethyl cellulose and carboxyl vinyl polymer (column 2 lines 45-50).

Jain et al teach the equivalence of cellulose alkyl hydroxylates in (tablet) cores, in particular that of hydroxypropyl cellulose and hydroxyl ethyl cellulose (column 5 lines 21-27).

It would have been obvious to one of ordinary skill to make a core comprising a carboxyl vinyl polymer and alkyl cellulose in view of Guley et al. As to the claimed

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hydroxy ethyl cellulose, Jain et al teach the equivalence of this hydroxypropyl cellulose<sup>x</sup>  
^  
of Guley et al in tablet cores.

As to the claimed magnesium stearate, Jain et al teach magnesium stearate as a<sup>g</sup>  
tableting lubricant (column 7 lines 44-45). It would have been obvious to add  
magnesium stearate to the composition of Guley et al as an additional lubricant in view  
of Jain et al.


Applicants argue that Jain et al do not teach a mixture of hydroxy alkyl celluloses.  
However, Jain et al is only used for its teaching of the above cited equivalence.  
Applicants next argue that Jain<sup>fs</sup>  
^ listing of alternative hydroxyalkyl celluloses does not  
constitute a showing of equivalence. However, a listing of these polymers in the  
alternative indicates that any one of them can be substituted for another in the list.  
Lastly, applicants cite a declaration as evidence of nonequivalence. However, none is  
of record as having been filed with applicants' remarks of 5/10/04.

No claims allowed.

Any inquiry concerning this communication should be directed to Edward J.  
Webman at telephone number 571-272-0633.

Webman/tgd

June 2, 2004

  
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